

## RULE ANALYSIS

**Introduction:** THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED RULE

**Short Title:** Floor Stock Documentation

**Rule Numbers:** §291.151

**Statutory Authority:** Texas Pharmacy Act, Chapter 551-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

**Purpose:** The amendments, if adopted, allow pharmacists to record certain information in the patient's chart in lieu of keeping a separate log.

**The Board reviewed and voted to propose the amendments during the May 3, 2016, meeting. The proposed amendments were published in the June 24, 2016, issue of the *Texas Register* at 41 TexReg 4617.**

1 **SUBCHAPTER H. OTHER CLASSES OF PHARMACY**

2 **22 TAC §291.151**

3 The Texas State Board of Pharmacy proposes amendments to §291.151 concerning Pharmacies  
4 Located in a Freestanding Emergency Medical Care Facility (Class F). The amendments, if  
5 adopted, clarify recordkeeping requirements and allow pharmacists to record certain information  
6 in the patient's chart in lieu of keeping a separate log.

7 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year  
8 period the rule is in effect, there will be no fiscal implications for state or local government as a  
9 result of enforcing or administering the rule.

10 Ms. Dodson has determined that, for each year of the first five-year period the rule will be in  
11 effect, the public benefit anticipated as a result of enforcing the amendments will ensure  
12 appropriate records are maintained by Class F Pharmacies located in freestanding emergency  
13 medical care facilities. There is no fiscal impact for individuals, small or large businesses, or to  
14 other entities which are required to comply with this section.

15 Written comments on the amendments may be submitted to Allison Vordenbaumen Benz, R.Ph.,  
16 M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street,  
17 Suite 3-600, Austin, Texas 78701, FAX (512) 305-6778. Comments must be received by 5:00  
18 p.m., August 1, 2016.

19 The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act  
20 (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the  
21 agency to protect the public through the effective control and regulation of the practice of  
22 pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the  
23 proper administration and enforcement of the Act.

24 The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas  
25 Occupations Code.

26 ***§291.151. Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F).***

27 (a) - (c) (No change.)

28 (d) Operational standards.

29 (1) Licensing requirements.

30 (A) A FEMCF pharmacy shall register annually or biennially with the board on a pharmacy  
31 license application provided by the board, following the procedures specified in §291.1 of this  
32 title (relating to Pharmacy License Application).

33 (B) A FEMCF pharmacy which changes ownership shall notify the board within 10 days of the  
34 change of ownership and apply for a new and separate license as specified in §291.3 of this title  
35 (relating to Required Notifications).

36 (C) A FEMCF pharmacy which changes location and/or name shall notify the board of the  
37 change within 10 days and file for an amended license as specified in §291.3 of this title.

38 (D) A pharmacy owned by a partnership or corporation which changes managing officers shall  
39 notify the board in writing of the names of the new managing officers within 10 days of the  
40 change, following the procedures in §291.3 of this title.

41 (E) A FEMCF pharmacy shall notify the board in writing within 10 days of closing, following  
42 the procedures in §291.5 of this title (relating to Closing a Pharmacy).

43 (F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged  
44 for issuance and renewal of a license and the issuance of an amended license.

45 (G) A separate license is required for each principal place of business and only one pharmacy  
46 license may be issued to a specific location.

47 (H) A FEMCF pharmacy, which also operates another type of pharmacy which would otherwise  
48 be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy  
49 (Class A), is not required to secure a license for the other type of pharmacy; provided, however,  
50 such license is required to comply with the provisions of §291.31 of this title (relating to  
51 Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to  
52 Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title  
53 (relating to Official Prescription Records), to the extent such sections are applicable to the  
54 operation of the pharmacy.

55 (I) A FEMCF pharmacy engaged in the compounding of non-sterile preparations shall comply  
56 with the provisions of §291.131 of this title.

57 (2) Environment.

58 (A) General requirements.

59 (i) Each FEMCF shall have a designated work area separate from patient areas, and which shall  
60 have space adequate for the size and scope of pharmaceutical services and shall have adequate  
61 space and security for the storage of drugs.

62 (ii) The FEMCF pharmacy shall be arranged in an orderly fashion and shall be kept clean. All  
63 required equipment shall be clean and in good operating condition.

64 (B) Special requirements.

- 65 (i) The FEMCF pharmacy shall have locked storage for Schedule II controlled substances and  
66 other controlled drugs requiring additional security.
- 67 (ii) The FEMCF pharmacy shall have a designated area for the storage of poisons and externals  
68 separate from drug storage areas.
- 69 (C) Security.
- 70 (i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed and  
71 capable of being locked by key, combination, or other mechanical or electronic means, so as to  
72 prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-  
73 charge may enter the pharmacy or have access to storage areas for prescription drugs and/or  
74 devices.
- 75 (ii) The pharmacist-in-charge shall consult with FEMCF personnel with respect to security of the  
76 drug storage areas, including provisions for adequate safeguards against theft or diversion of  
77 dangerous drugs, controlled substances, and records for such drugs.
- 78 (iii) The pharmacy shall have locked storage for Schedule II controlled substances and other  
79 drugs requiring additional security.
- 80 (3) Equipment and supplies. FEMCFs supplying drugs for outpatient use shall have the following  
81 equipment and supplies:
- 82 (A) data processing system including a printer or comparable equipment;
- 83 (B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and
- 84 (C) adequate supply of prescription labels and other applicable identification labels.
- 85 (4) Library. A reference library shall be maintained that includes the following in hard-copy or  
86 electronic format and that pharmacy personnel shall be capable of accessing at all times:
- 87 (A) current copies of the following:
- 88 (i) Texas Pharmacy Act and rules;
- 89 (ii) Texas Dangerous Drug Act and rules;
- 90 (iii) Texas Controlled Substances Act and rules; and
- 91 (iv) Federal Controlled Substances Act and rules or official publication describing the  
92 requirements of the Federal Controlled Substances Act and rules;

- 93 (B) at least one current or updated general drug information reference which is required to  
94 contain drug interaction information including information needed to determine severity or  
95 significance of the interaction and appropriate recommendations or actions to be taken; and
- 96 (C) basic antidote information and the telephone number of the nearest regional poison control  
97 center.
- 98 (5) Drugs.
- 99 (A) Procurement, preparation, and storage.
- 100 (i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of  
101 drugs, but may receive input from other appropriate staff of the facility, relative to such  
102 responsibility.
- 103 (ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all  
104 drugs procured by the facility.
- 105 (iii) FEMCF pharmacies may not sell, purchase, trade, or possess prescription drug samples,  
106 unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to  
107 Samples).
- 108 (iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in  
109 §291.15 of this title (relating to Storage of Drugs).
- 110 (v) Any drug bearing an expiration date may not be dispensed or distributed beyond the  
111 expiration date of the drug.
- 112 (vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined together  
113 until such drugs are disposed of.
- 114 (B) Formulary.
- 115 (i) A formulary may be developed by an appropriate committee of the FEMCF.
- 116 (ii) The pharmacist-in-charge, consultant pharmacist, or designee shall be a full voting member  
117 of any committee which involves pharmaceutical services.
- 118 (iii) A practitioner may grant approval for pharmacists at the FEMCF to interchange, in  
119 accordance with the facility's formulary, for the drugs on the practitioner's medication orders  
120 provided:
- 121 (I) a formulary has been developed;
- 122 (II) the formulary has been approved by the medical staff of the FEMCF;

- 123 (III) there is a reasonable method for the practitioner to override any interchange; and
- 124 (IV) the practitioner authorizes pharmacist in the FEMCF to interchange on his/her medication  
125 orders in accordance with the facility's formulary through his/her written agreement to abide by  
126 the policies and procedures of the medical staff and facility.
- 127 (C) Prepackaging and loading drugs into automated medication supply system.
- 128 (i) Prepackaging of drugs.
- 129 (I) Drugs may be prepackaged in quantities suitable for internal distribution only by a pharmacist  
130 or by pharmacy technicians or pharmacy technician trainees under the direction and direct  
131 supervision of a pharmacist.
- 132 (II) The label of a prepackaged unit shall indicate:
- 133 (-a-) brand name and strength of the drug; or if no brand name, then the generic name, strength,  
134 and name of the manufacturer or distributor;
- 135 (-b-) facility's lot number;
- 136 (-c-) expiration date; and
- 137 (-d-) quantity of the drug, if quantity is greater than one.
- 138 (III) Records of prepackaging shall be maintained to show:
- 139 (-a-) the name of the drug, strength, and dosage form;
- 140 (-b-) facility's lot number;
- 141 (-c-) manufacturer or distributor;
- 142 (-d-) manufacturer's lot number;
- 143 (-e-) expiration date;
- 144 (-f-) quantity per prepackaged unit;
- 145 (-g-) number of prepackaged units;
- 146 (-h-) date packaged;
- 147 (-i-) name, initials, or electronic signature of the packer; and
- 148 (-j-) signature or electronic signature of the responsible pharmacist.

149 (IV) Stock packages, repackaged units, and control records shall be quarantined together until  
150 checked/released by the pharmacist.

151 (ii) Loading bulk unit of use drugs into automated medication supply systems. Automated  
152 medication supply systems may be loaded with bulk unit of use drugs only by a pharmacist or by  
153 pharmacy technicians or pharmacy technician trainees under the direction and direct supervision  
154 of a pharmacist. For the purpose of this clause, direct supervision may be accomplished by  
155 physically present supervision or electronic monitoring by a pharmacist. In order for the  
156 pharmacist to electronically monitor, the medication supply system must allow for bar code  
157 scanning to verify the loading of drugs, and a record of the loading must be maintained by the  
158 system and accessible for electronic review by the pharmacist.

159 (6) Medication orders.

160 (A) Drugs may be administered to patients in FEMCFs only on the order of a practitioner. No  
161 change in the order for drugs may be made without the approval of a practitioner except as  
162 authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.

163 (B) Drugs may be distributed only pursuant to the copy of the practitioner's medication order.

164 (C) FEMCF pharmacies shall be exempt from the labeling provisions and patient notification  
165 requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to  
166 medication orders.

167 (D) In FEMCFs with a full-time pharmacist, if a practitioner orders a drug for administration to a  
168 bona fide patient of the facility when the pharmacy is closed, the following is applicable.

169 (i) Prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of  
170 a patient may be removed from the FEMCF pharmacy.

171 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.

172 (iii) A record shall be made at the time of withdrawal by the authorized person removing the  
173 drugs and devices. The record shall contain the following information:

174 (I) name of the patient;

175 (II) name of device or drug, strength, and dosage form;

176 (III) dose prescribed;

177 (IV) quantity taken;

178 (V) time and date; and

179 (VI) signature or electronic signature of person making withdrawal.

- 180 (iv) The medication order in the patient's chart may substitute for such record, provided the  
181 medication order meets all the requirements of clause (iii) of this subparagraph.
- 182 (v) The pharmacist shall verify the withdrawal as soon as practical, but in no event more than 72  
183 hours from the time of such withdrawal.
- 184 (E) In FEMCFs with a part-time or consultant pharmacist, if a practitioner orders a drug for  
185 administration to a bona fide patient of the FEMCF when the pharmacist is not on duty, or when  
186 the pharmacy is closed, the following is applicable.
- 187 (i) Prescription drugs and devices only in sufficient quantities for therapeutic needs may be  
188 removed from the FEMCF pharmacy.
- 189 (ii) Only a designated licensed nurse or practitioner may remove such drugs and devices.
- 190 (iii) A record shall be made at the time of withdrawal by the authorized person removing the  
191 drugs and devices; the record shall meet the same requirements as specified in subparagraph (D)  
192 of this paragraph.
- 193 (iv) The pharmacist shall conduct an audit of patient's medical record according to the schedule  
194 set out in the policy and procedures at a reasonable interval, but such interval must occur at least  
195 once in every calendar week that the pharmacy is open.
- 196 (7) Floor stock. In facilities using a floor stock method of drug distribution, the following is  
197 applicable for removing drugs or devices in the absence of a pharmacist.
- 198 (A) Prescription drugs and devices may be removed from the pharmacy only in the original  
199 manufacturer's container or prepackaged container.
- 200 (B) Only a designated licensed nurse or practitioner may remove such drugs and devices.
- 201 (C) A record shall be made at the time of withdrawal by the authorized person removing the drug  
202 or device; the record shall contain the following information:
- 203 (i) name of the drug, strength, and dosage form;
- 204 (ii) quantity removed;
- 205 (iii) location of floor stock;
- 206 (iv) date and time; and
- 207 (v) signature or electronic signature of person making the withdrawal.
- 208 (D) A pharmacist shall verify the withdrawal according to the following schedule.

209 (i) In facilities with a full-time pharmacist, the withdrawal shall be verified as soon as practical,  
210 but in no event more than 72 hours from the time of such withdrawal.

211 (ii) In facilities with a part-time or consultant pharmacist, the withdrawal shall be verified after a  
212 reasonable interval, but such interval must occur at least once in every calendar week that the  
213 pharmacy is open.

214 (iii) The medication order in the patient's chart may substitute for the record required in  
215 subparagraph (C) of this paragraph, provided the medication order meets all the requirements of  
216 subparagraph (C) of this paragraph.

217 (8) Policies and procedures. Written policies and procedures for a drug distribution system,  
218 appropriate for the freestanding emergency medical facility, shall be developed and implemented  
219 by the pharmacist-in-charge with the advice of the appropriate committee. The written policies  
220 and procedures for the drug distribution system shall include, but not be limited to, procedures  
221 regarding the following:

222 (A) controlled substances;

223 (B) investigational drugs;

224 (C) prepackaging and manufacturing;

225 (D) medication errors;

226 (E) orders of physician or other practitioner;

227 (F) floor stocks;

228 (G) adverse drug reactions;

229 (H) drugs brought into the facility by the patient;

230 (I) self-administration;

231 (J) emergency drug tray;

232 (K) formulary, if applicable;

233 (L) drug storage areas;

234 (M) drug samples;

235 (N) drug product defect reports;

236 (O) drug recalls;

- 237 (P) outdated drugs;
- 238 (Q) preparation and distribution of IV admixtures;
- 239 (R) procedures for supplying drugs for postoperative use, if applicable;
- 240 (S) use of automated medication supply systems;
- 241 (T) use of data processing systems; and
- 242 (U) drug regimen review.
- 243 (9) Drugs supplied for outpatient use. Drugs provided to patients for take home use shall be  
244 supplied according to the following procedures.
- 245 (A) Drugs may only be supplied to patients who have been admitted to the FEMCF.
- 246 (B) Drugs may only be supplied in accordance with the system of control and accountability  
247 established for drugs supplied from the FEMCF; such system shall be developed and supervised  
248 by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.
- 249 (C) Only drugs listed on the approved outpatient drug list may be supplied; such list shall be  
250 developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the  
251 nature and type to meet the immediate postoperative needs of the FEMCF patient.
- 252 (D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in  
253 suitable containers and appropriately pre-labeled (including name, address, and phone number of  
254 the facility and necessary auxiliary labels) by the pharmacy, provided, however that topicals and  
255 ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-  
256 hour supply.
- 257 (E) At the time of delivery of the drug, the practitioner shall complete the label, such that the  
258 prescription container bears a label with at least the following information:
- 259 (i) date supplied;
- 260 (ii) name of practitioner;
- 261 (iii) name of patient;
- 262 (iv) directions for use;
- 263 (v) brand name and strength of the drug; or if no brand name, then the generic name of the drug  
264 dispensed, strength, and the name of the manufacturer or distributor of the drug; and
- 265 (vi) unique identification number.

266 (F) After the drug has been labeled, the practitioner or a licensed nurse under the supervision of  
267 the practitioner shall give the appropriately labeled, prepackaged medication to the patient.

268 (G) A perpetual record of drugs which are supplied from the FEMCF shall be maintained which  
269 includes:

270 (i) name, address, and phone number of the facility;

271 (ii) date supplied;

272 (iii) name of practitioner;

273 (iv) name of patient;

274 (v) directions for use;

275 (vi) brand name and strength of the drug; or if no brand name, then the generic name of the drug  
276 dispensed, strength, and the name of the manufacturer or distributor of the drug; and

277 (vii) unique identification number.

278 (H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall  
279 review the records at least once in every calendar week that the pharmacy is open.

280 (10) Drug regimen review.

281 (A) A pharmacist shall evaluate medication orders and patient medication records for:

282 (i) known allergies;

283 (ii) rational therapy--contraindications;

284 (iii) reasonable dose and route of administration;

285 (iv) reasonable directions for use;

286 (v) duplication of therapy;

287 (vi) drug-drug interactions;

288 (vii) drug-food interactions;

289 (viii) drug-disease interactions;

290 (ix) adverse drug reactions;

- 291 (x) proper utilization, including overutilization or underutilization; and
- 292 (xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug  
293 effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of  
294 the drug in its current regimen.
- 295 (B) A retrospective, random drug regimen review as specified in the pharmacy's policies and  
296 procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed  
297 31 days between such reviews.
- 298 (C) Any questions regarding the order must be resolved with the prescriber and a written  
299 notation of these discussions made and maintained.
- 300 (e) (No change.)